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July 25, 2001

Kimberly Topper

Food and Drug Administration, CDER
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Topper:

I am writing this letter on behalf of the Federation of State Medical Boards in order to submit written testimony for the September 13-14, 2001 meeting of the Anesthetic and Life Support Drugs Advisory Committee.

The Federation of State Medical Boards of the United States (FSMB) is a non-profit organization comprised of 70 medical and osteopathic licensing and disciplinary boards of the United States and its territories. As such, the Federation is positioned as a leader in medical licensure and discipline and an authoritative source of research, policy development, education, and information. The Federation's primary mission is to improve the quality, safety, and integrity of health care by supporting and assisting state medical boards in the protection of the public.

Enclosed are copies of our *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, and a position paper on the Federation's pain management policy, which we would like to submit as written testimony for the record. The Model Guidelines reflect currently accepted standards that may be used by both medical professionals and regulators in determining the appropriateness of opioid prescribing. These Guidelines have been adopted by many state medical boards, and endorsed by the American Pain Society, National Association of Boards of Pharmacy, and the American Academy of Pain Medicine.

Thank you for allowing the Federation to submit these items for the record.

Sincerely,

Dale L. Austin
Interim Chief Executive Officer

DLA/rda
Enclosures

POSITION OF THE FEDERATION OF STATE MEDICAL BOARDS IN SUPPORT OF ADOPTION OF PAIN MANAGEMENT GUIDELINES

Background and Statement of the Problem

Recent years have seen increased public demand for improvement in medical management of pain, concurrent with advances in medical knowledge regarding the use of controlled substances (including opioids) in the treatment of cancer and chronic non-cancer pain. While committed to ensuring the public has access to physicians competent in providing effective pain management, state medical boards have a duty to protect the public from endangerment by physicians who improperly use and prescribe controlled substances.

Physician fear of investigation and/or disciplinary action by state and federal regulatory agencies for prescribing opioids to manage long-term pain may be a significant factor in inadequate pain control and unnecessary patient suffering. In addition, physician perception that regulatory processes are confusing and potentially restrict their ability to appropriately prescribe for chronic pain management also contributes to inadequate pain control, as does lack of knowledge of current and accepted standards for practice. Clearly, the need existed for consistent standards regulating the use of controlled substances in the management of chronic malignant and non-malignant pain to be adopted or developed, especially in states where none exist.

Call to Action

The Federation initiated a project in 1997 to develop model guidelines to assist state medical boards and other healthcare regulatory boards in promoting the appropriate use of controlled substances in the management of chronic cancer and non-cancer pain. The project was developed in collaboration with the American Society of Law, Medicine and Ethics, the American Pain Society, the American Academy of Pain Medicine, the University of Wisconsin Pain and Policies Studies Group, pharmaceutical companies, and state medical boards. This diverse group allowed varied perspectives to be considered in the drafting and development of the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

The Federation's House of Delegates adopted the *Model Guidelines* as policy in May 1998, and over 144,000 copies have been distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, and state and federal regulatory agencies. Many states have used the Federation's *Model Guidelines* in drafting their guidelines and some states have chosen to adopt the *Model*

Guidelines in their entirety. As of January 31, 2001, only seven (7) states have no guidelines or law addressing pain management.¹

The guidelines adopted by the Federation's House of Delegates in 1998 promote public health by facilitating the provision of adequate and effective pain control and educating the medical community on treating chronic pain within the bounds of professional practice. Adoption of guidelines assist in educating licensees about the legitimate medical uses of controlled substances and limit potential drug diversion and inappropriate prescribing practices.²

Creating uniform standards for use by boards in evaluating cases involving controlled substances for pain management accomplishes two goals: (1) protecting the public from the substandard use of controlled substances in the treatment of cancer and chronic non-cancer pain; and (2) improvement in public access to appropriate and effective pain relief.

Medical boards in states where no guidelines or laws exist are encouraged to use the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* as a reference source in developing pain guidelines and or policy. Additionally, the Federation encourages all medical boards to use the Federation's *Model Guidelines* as a reference source in evaluating their existing pain policies or statutes to assure currency and consistency of standards in the management of chronic pain.

The Federation promotes a non-legislative approach in improving the regulation of physicians prescribing controlled substances in the treatment of pain. Legislative action may hinder the appropriate management of pain by physicians through unnecessary requirements and could supplant the authority of state medical boards to improve the quality of care available to patients within their jurisdictions. Thus, state medical boards should be proactive in the promotion of pain management policy initiatives to preclude legislative intervention.

¹ PPSG United States Policy. www.medsch.wisc.edu/painpolicy

² *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, 1998